MARYLAND PHARMACY WAIVER PERMIT APPLICATION INSTRUCTIONS

- Complete the attached Maryland Board of Pharmacy's **Application for Maryland Pharmacy Waiver Permit**. The box for the relevant application type (New, New Ownership, New Location, Renewal, Late Renewal, or Reinstatement) must be selected.

> **NOTE:** A Waiver Pharmacy must limit practice only to the specialty specified on the waiver application. This means the pharmacy cannot perform pharmaceutical services other than those allowed by the restrictive waiver.

- Submit the completed application with all attachments and a check made payable to the Maryland Board of Pharmacy in the appropriate amount to:

Maryland Board of Pharmacy, PO BOX 2024, Baltimore, MD 21203-2024.

- Applications sent overnight or through priority mail must be addressed to the appropriate lockbox and sent to:

Wells Fargo Bank, Attn: State of MD – Board of Pharmacy, Lockbox 2024
7175 Columbia Gateway Drive, Columbia, MD 21046

  - An application fee of **$ 700.00** is required for a New Pharmacy permit or changes to the Pharmacy permit.
  - An application fee of **$ 500.00** is required for a Pharmacy Permit Renewal.
  - An application fee of **$ 700.00** ($500 renewal fee + $200 late fee) shall be paid to the Board if a renewal application is post-marked between May 2nd and May 31st.
  - An application fee of **$ 1,050.00** ($500 renewal fee + $550 reinstatement fee) shall be paid to the Board if a renewal application is post-marked after May 31st.

The application process must be completed within one year from submission of the initial application. Applicants failing to complete the process within one year will be required to submit a new application and fee. Fees paid for applications that have expired will not be refunded or credited.

> **NOTE:** To determine if a pharmacy is eligible as a waiver pharmacy, the Board shall consider whether:
> (1) The pharmaceutical specialty service is necessary to meet a specific therapeutic need;
> (2) The location is accessible without endangering public health and safety;
> (3) The pharmacy is properly equipped to perform the pharmaceutical specialty; and
> (4) The applicant has provided a full and detailed description of the pharmaceutical specialty that clearly substantiates the basis for the request of a waiver permit.

NOTE: Durable Medical Equipment (DME)/Device providers located in Maryland that dispense DME/Devices only are **NOT** required to have a permit. A completed application must include:

- Copies of all federal and state licenses, registrations, and/or permits;
- Floor plan diagram of the pharmacy and all decentralized pharmacies;
- A list of all disciplinary actions taken by federal and/or state agencies against the pharmacy, pharmacy employees or any principals, owners, directors, or officers;
- The appropriate application fee ($700 for New, New Ownership and New Location, $500 for Renewal, $700 for late Renewal, and $1,050 for Reinstatement applications); and
- Any other documentation required in HO §12–404.

- For renewing applicants **(MARYLAND ONLY)**:
  - **DO NOT attach the following requested attachments when submitting your application:**
    - Most recent Maryland Board of Pharmacy inspection
    - Pharmacy floor plan
    - Copy of pharmacist license(s)
    - Copy of pharmacy technician license(s).
  - **Please attach a list of names and permit numbers for all currently employed pharmacists and pharmacy technicians.**
  - **ALL OTHER REQUESTED ATTACHMENTS MUST BE ATTACHED.**

- If the actual date of the opening or change is different from the Proposed Date of Opening or Ownership/Location Change on the application, please contact the Board as soon as possible and provide the new date.

- All Maryland businesses must pay Maryland Unemployment and Use & Sales taxes before their permit can be renewed. To settle a past business tax liability, call 410-649-0633 in Central Maryland or toll-free at 1-888-614-6337.

- Before returning your completed application to the Board of Pharmacy, it is recommended that you maintain a copy of your submission and attachments for your records.

NOTE: The Board must be notified of any change in the pharmacy name, ownership, location, or decentralized pharmacy within thirty (30) days of the change, if the change occurs before the bi-annual renewal.

NOTE: Please allow four to six weeks for the Board to process your completed application.

NOTE: The application fee is a non-refundable, administrative fee.

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore MD 21215-2299
Phone: 410-764-4755
Fax: 410-358-6207
www.dhmh.maryland.gov/pharmacy

APPLICATION FOR PHARMACY WAIVER PERMIT

- Please print clearly in ink or type in upper case letters only.
- Complete all application sections and sign. If a question is not applicable, an explanation must be provided. Incomplete forms will delay the issuance of your permit.

APPLICATION TYPE					
☐ **New Application** **Fee: $700.00**	☐ **New Ownership** **Fee: $700.00**	☐ **New Location** **Fee: $700.00**	☐ **Renewal** **Fee: $500.00**	☐ **Late Renewal** **Fee: $700.00**	☐ **Reinstatement** **Fee: $1,050.00**

1. APPLICANT INFORMATION	
A. Name of Applicant: ***(name in which company is doing business)***	
Maryland Permit Number *(if applicable)*:	

B. Facility Address *(physical location of establishment which should be reflected on all sales invoices and shipping documents)*:					
Street Address:				**Suite #:**	
City:		**State:**		**Zip Code:**	
Telephone #:				**Fax #:**	
Web Site:		**Email Address:**			
Federal Tax ID #:					

C. Date of Proposed Opening or Ownership / Location Change	

D. Type of Business (check all that apply):		
☐Sole Proprietorship	☐Partnership	☐C Corporation
☐S Corporation	☐LLC	☐Other (please explain): _____
If the Pharmacy is a Corporation, check the appropriate box:	☐Non-Public	☐Public

E. Date Business was Established:	

F. Is this the first application that you have submitted for this facility?	☐YES ☐NO
If not, provide the date of the most recent submission:	

G. If this application is being submitted for an ownership change, provide the name of the previous owner:	

2. FACILITY INFORMATION	
A. Date of last inspection by a state agency, accreditation program, or FDA: ***(attach most recent inspection report. Renewal applicants do <u>not</u> have to provide the most recent inspection report)***	

B. DEA Registration #:		**Expiration Date:**	
Maryland CDS Registration # ***(attach copies of registration certificates)***		**Expiration Date:**	

C.	**State and Federal permit/license/registration numbers** ***(Include a copy of the permit/license/registration) (attach additional pages if necessary)*:**
LICENSING BODY	**PERMIT / LICENSE / REGISTRATION NUMBER**

D. Does this Corporation, Partnership or Individual have a subsidiary or other affiliate located in Maryland?	☐YES ☐NO
If YES, provide the company name:	
Company address	
Permit #:	

3. OPERATIONS			
A. Hours of Operation			
Sunday		**Thursday**	
Monday		**Friday**	
Tuesday		**Saturday**	
Wednesday			

B. CHECK ALL APPLICABLE DESCRIPTIONS OF THE PHARMACY:		
☐ Assisted Living	☐ Comprehensive Care Facility	☐ Developmental Disabilities Facility
☐ Durable Medical Equipment (DME) / Device	☐ Home Infusion	☐ Inpatient Hospital
☐ Non Sterile Compounding	☐ Nuclear Pharmaceutical	☐ Pharmaceutical services across all settings of care within a continuing care in a retirement community
☐ Research	☐ Sterile Compounding	☐ Veterinary Care
☐ 340 B	☐ Other services *(if checked answer questions i-vi* below)*	

i. Why is the pharmaceutical specialty service necessary to meet a specific therapeutic need?

ii. I attest that the location is accessible without endangering public health and safety.

Initial: _____

iii. I attest that the pharmacy is properly equipped to perform the pharmaceutical specialty.

Initial: _____

iv. Provide a full and detailed description of the pharmaceutical specialty that clearly substantiates the basis for the request of a waiver permit. (add additional page(s) if necessary)

v. A policy and procedure manual, which will be provided upon request, sets forth a detailed description of the pharmacy operation.

Initial: _____

vi. Describe the group or groups the applicant will serve.

C. Explain any unusual specialized setting (such as equipment, systems, location, or physical structure) that the applicant will use. (add additional page(s) if necessary)

D. Provide information that demonstrates a need in the community for the specialized type of pharmacy. (add additional page(s) if necessary)

E. Does this Pharmacy conduct business on the Internet?	☐YES ☐NO
If YES, what services?	
Is your business address and telephone number specified on your website(s)?	☐YES ☐NO

F. What other business website name(s) does this establishment use, other than that listed in the applicant information section or the previous question?

G. What reference materials are kept in the pharmacy reference library?

4. OWNERSHIP	
Please include the following on a separate sheet:	
1. Full name, title, date of birth, and business address for owner, sole proprietor, each partner, and/or each corporate director or officer;	
2. Full name, title, date of birth, and business address for each manager of an LLC;	
3. Full name, title, date of birth and business address for each shareholder owning 10% or more of the shares for a *non-publicly traded corporation*; and	
4. Corporate name for a non-publicly traded corporation.	
5. Are any of the owners licensed in any other healthcare profession?	☐YES ☐NO
If yes, provide the names of these owners along with their corresponding licensed profession, state license number, and expiration date.	
6. Do you currently or have you ever owned, in whole or in part, another pharmacy or distributor entity? If so, please list establishment name, location, and permit number.	

NAME OF THE OWNER	TYPE OF HEALTHCARE PROFESSION	STATE LICENSE #	EXP. DATE

5. DISCIPLINARY ACTIONS

Please include a separate sheet listing all disciplinary actions by federal or state agencies against the pharmacy, as well as any such actions against principals, owners, directors, officers, or employees. Please include documentation of any corrective actions taken in response to any disciplinary actions and any final orders issued by any federal or state agencies. **Renewal, relocation, and reinstatement applicants - please only include information since the last application you submitted to the Board.**

Attachment included:	☐YES ☐NO

6. PERSONNEL

A.	**The Worker's Compensation Law (Art. 101 Sec. 1-102) requires that you carry workman's compensation insurance for two or more employee, including the permit holder.**	
	Worker's Compensation Number:	

B.	**The number of staff employed at this location:**	
	(1) Number of Pharmacists:	
	(2) Number of Pharmacy Technicians:	
	(3) Number of Pharmacy Interns:	
	(4) Number of Unlicensed/Unregistered Personnel in the Pharmacy:	

C. Complete pharmacist, pharmacy interns, and pharmacy technician employees' name(s), employment status, license/registration number and expiration date. Attach additional sheets if necessary

EMPLOYEE NAME	FULL / PART-TIME	STATE LICENSE / REGISTRATION #	EXPIRATION DATE
	☐ F/T ☐P/T		
	☐ F/T ☐P/T		
	☐ F/T ☐P/T		
	☐ F/T ☐P/T		
	☐ F/T ☐P/T		
	☐ F/T ☐P/T		

The Board must be notified in 30 days of any changes in pharmacist/pharmacy intern/pharmacy technician employment.

D. Describe the current method of verifying the expiration dates of licensure/registration for pharmacy employees:

E. Provide the name and contact information for the person responsible for verifying employee licensure/registration information:			
NAME	**TITLE**	**TELEPHONE #**	**EMAIL**

7. MARYLAND LAWS & REGULATIONS ATTESTATION

In order to operate as a Maryland pharmacy in Maryland, the permit holder must certify that the pharmacy is equipped with sanitary appliances such as toilets, plumbing, running water, lighting, etc. in order to maintain the premises in a clean and orderly manner. In addition, the pharmacy must meet the requirements of the Code of Maryland Regulations regarding pharmacy equipment (COMAR 10.34.07).

By signing this application, I solemnly affirm under the penalties of perjury that the contents of this application are true to the best of my knowledge, information, and belief. I further certify that I am aware of and will meet the requirements of the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Maryland Waiver Pharmacy Permitting. I understand that a Maryland Waiver Pharmacy Permit may be revoked if any statement made in this application is found to be false.

Signature of Legal Applicant:			
Business Telephone #:		**Business Fax #:**	
Name and Title:		**Email Address:**	
Corporation Name:		**Date:**	

8. LIST OF DESIGNEE

If applicable, list the names of person and/or entity that you authorize the Board to release information about your application:

Name of Organization	Name of Person	Title

9. ATTESTATION FOR REINSTATEMENT APPLICANTS ONLY			
I hereby swear and affirm under penalty of perjury that [insert pharmacy], _____ permit no. _____, has not operated as a pharmacy in the State of Maryland since the expiration of our most recent pharmacy permit, which expired on _____. I understand that a violation of Md. Code. Ann., Health Occ.. § 12-703 or its corresponding regulations may result in the imposition of a fine not to exceed $50,000.			
Signature of Permit Holder:			
Printed Name of Permit Holder:		**Date:**	

10. APPLICATION CHECKLIST		
Application Fee ($500, $700, or $1,050)	☐YES	☐NO
Most Recent Inspection Report (If applicable)	☐YES	☐NO
Copies of DEA & Maryland CDS Registration Certificates	☐YES	☐NO
Copy of Permit(s) from State of Residence	☐YES	☐NO
Ownership Information	☐YES	☐NO
Floor plan diagram of the pharmacy (size 8 ½ x 11)	☐YES	☐NO